

**REMARKS/ARGUMENTS**

Favorable reconsideration of this application is requested in view of the remarks which follow.

**I. Disposition of Claims**

Claim 46, 48, 51, and 53-60 are pending in this application.

**II. Examiner Request/Observation**

Support for the claim limitation "the first membrane consisting essentially of a hydrophobic substance and a hydrophilic substance exhibiting an aqueous solubility responsive to osmotic pressure and/or ionic strength of said formulation" can be found on page 10, lines 25-29 of the instant application. This passage is reproduced below for the Examiner's convenience:

"Compositions for forming interior wall 16 comprise a hydrophobic substance and a hydrophilic substance, wherein the hydrophilicity of the hydrophilic substance is osmosensitive. Preferably, the hydrophilic substance exhibits an aqueous solubility responsive to osmotic pressure and/or ionic strength of the osmotic core." The above-excerpt from the instant specification supports the Applicants last amendment, in which claim 46 recites "the first membrane consisting essentially of a hydrophobic substance and a hydrophilic substance exhibiting an aqueous solubility responsive to osmotic pressure and/or ionic strength of said formulation."

**III. Rejections under 35 U.S.C. §102****A. Chen *et al.* (U.S. Patent No. 5,558,879)**

Claims 46, 48, 51, 53-58, and 60 were rejected under 35 U.S.C. §102(b) as being anticipated by Chen *et al.* Reconsideration of the rejection of claims 46, 48, 51, 53-58, and 60 is respectfully requested.

Claim 46 was previously amended to recite that "the first membrane consisting essentially of a hydrophobic substance and a hydrophilic substance exhibiting an aqueous solubility responsive to osmotic pressure and/or ionic strength of said formulation." The

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Examiner acknowledges that Chen *et al.* is only considered to disclose a hydrophilic substance. However, the Examiner erroneously asserts that "instant claim 1 is directed to hydrophobic *or* hydrophilic substance that responds to osmotic pressure." (See p. 3 of the Office Action dated December 28, 2004). To the contrary, Chen *et al.* must show both "a hydrophobic substance *and* hydrophilic substance" as recited by claim 46, because of the use of the phrase "consisting essentially of" in the claim language. As stated by the Federal Circuit:

"Consisting essentially of" is a transitional phrase commonly used to signal a partially open claim in a patent. Typically, "consisting essentially of" precedes a list of ingredients in a composition claim or a series of steps in a process claim. By using the term "consisting essentially of" the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A "consisting essentially of" claim occupies a middle ground between closed claims that are written in a "consisting of" format and fully open claims that are drafted in a "comprising format." (PPG Indus v. Guardian Indus. Corp., 156 F.3d 1351, 48 USPQ2d 1351, 1353 (Fed. Cir. 1998) (citing Ex parte Davis, 80 USPQ 448, 449-50 (Pat. Off. Bd. App. 1948); MPEP §2111.03 (6th ed. 1997)).)

In other words, the Federal Circuit emphasizes that the use of the phrase "consisting essentially of," as recited in claim 46, indicates that the invention *necessarily* includes all of the ingredients listed thereafter, namely, "a hydrophobic substance *and* a hydrophilic substance" in this case.

Because the Examiner acknowledges that Chen *et al.* do not disclose both the hydrophobic substance and hydrophilic substance, as required by the claims, it is clear that Chen *et al.* do not anticipate the invention as recited claim 46. Withdrawal of the rejection of claim 46 over Chen *et al.* is respectfully requested. Claims 48, 51, and 53-58, which depend from claim 46, are likewise patentable over Chen *et al.* Claim 60, which recites a method of delivering a therapeutic agent to the subject comprising administering the dosage form of claim 46, is also patentable in view of the foregoing arguments.

**B. Bartoo *et al.* (U.S. Patent No. 4,743,248)**

Claims 46, 48, 51, and 53-60 were rejected under 35 U.S.C. §102(b) as being anticipated by Bartoo *et al.* Reconsideration of the rejection of claims 46, 48, 51, and 53- 60 is respectfully requested.

Claim 46 was previously amended to recite that "the first membrane consisting essentially of a hydrophobic substance and a hydrophilic substance exhibiting an aqueous solubility responsive to osmotic pressure and/or ionic strength of said formulation." The Examiner acknowledges that Bartoo *et al.* do not disclose both a hydrophobic substance and a hydrophilic substance. Further, the Examiner asserts that "the scope of the instant claim 46 is possibility between hydrophobic substance and a hydrophilic substance and Bartoo does not have to disclose both. Bartoo only has to disclose one." To the contrary, Bartoo *et al.* must show both "a hydrophobic substance *and* hydrophilic substance" as recited by claim 46, because of the use of the phrase "consisting essentially of" in the claim language.

As discussed above, because the Examiner acknowledges that Bartoo *et al.* do not disclose both the hydrophobic substance and hydrophilic substance, as required by the claims, it is clear that Bartoo *et al.* do not anticipate the invention as recited claim 46. Withdrawal of the rejection of claim 46 over Bartoo *et al.* is respectfully requested. Claims 48, 51, and 53-59, which depend from claim 46, are likewise patentable over Bartoo *et al.* Claim 60, which recites a method of delivering a therapeutic agent to the subject comprising administering the dosage form of claim 46, is also patentable in view of the foregoing arguments.

**IV. Conclusion**

The rejected claims have been amended and/or shown to be allowable over the prior art. Applicant believes that this paper is fully responsive to each ground of rejection cited by the Examiner in the Office Action dated December 28, 2004, and respectfully requests that a timely Notice of Allowance be issued in this case.

Please apply any charges not covered or credits in connection with this filing to Deposit Account No. 50-3202 (ref. ARC 2762C1).

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Respectfully submitted,

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Adenike Adebiyi

Adenike A. Adebiyi  
Reg. No. 42,254  
Tel.: (281) 440-1712